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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
AHMED, SHEEBA	
ART UNIT	PAPER NUMBER
1773	

DATE MAILED: 08/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/827,887	CLAUDE ET AL.	
	Examiner	Art Unit	
	Sheeba Ahmed	1773	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *23-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-22, drawn to a coated medical device, classified in class 428, subclass 332+.

   II. Claims 23-32, drawn to a method of coating a medical device, classified in class 427, subclass 2.3.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the coated medical device can be made by a process other than plasma polymerizing the coating onto the substrate. For example, the medical device may be coated by solution casting the coated material or by bonding the coating layer onto the substrate via an adhesive.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Gunter Hank on May 7, 2002, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-22. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 23-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1-9, 11, 14, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Okuda et al. (US 6,053,939).

Okuda et al. disclose an artificial blood vessel ***(corresponding to the medical device of claim 1 or the vascular graft of claim 14)*** comprising a tube ***(corresponding to the substrate of the claimed*** **invention)** formed of expanded polytetrafluoroethylene (EPTFE) ***(thus meeting the limitations of claim 9)*** comprising fibrils and nodes connecting the fibrils ***(thus meeting the limitations of claim 11)*** wherein the surfaces of said tube are rendered hydrophilic and a tissue-inducing

substance ***(corresponding to th bioactive agent of claims 7 and 8)*** is immobilized on the surface made hydrophilic (Column 2, lines 45-56). The EPTFE tube is immersed in a solution of methacrylic acid such that the polymethacrylic acid is grafted onto the EPTFE ***(thus meeting the limitations of claims 3-5)*** and then the EPTFE tube may be dipped in a tissue-inducing substance to covalently bond the tissue-inducing substance to the EPTFE (Column 5, lines 28-49). Other functional groups that may be introduced onto the EPTFE tube include carboxyl, hydroxyl and amino groups ***(thus meeting the limitations of claim 2)*** (Column 3, lines 49-52). The Examiner takes the position that the portion of the EPTFE tube beneath the grafted surface corresponds to the polymer bulk film of claim 6. Furthermore, the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see MPEP 2113.* In this case, the product (i.e., the medical device) is the same despite the process limitation of plasma polymerizing the functionalized coating. All limitations of the claimed invention are either inherent or disclosed in the above reference.

3. Claims 1-9 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhong (US 6,099,563).

Zhong discloses bioactive substrate coatings for medical devices, which enhance the antithrombogenic nature of such devices (Column 1, lines 15-22). The substrate is

coated with a polymer containing an organic functional group and a crosslinking agent, the coating is dried and crosslinked ***(thus meeting the limitations of claim 5)*** and then a bioactive surface coating is formed on the first coating ***(thus meeting the limitations of claim 7 and 8)*** and dried to covalently bond the organic functional groups of the bioactive agent to the first polymeric coating (Column 4, lines 29-49). The first organic functional group containing coating may comprise carboxyl groups or may be a polyacrylate ***(thus meeting the limitations of claims 2-4)*** (Column 5, lines 14-34).The substrate may be polytetrafluorethylene or nylon ***(thus meeting the limitations of claim 9)***. These bioactive coating are especially suited for coating at least a portion of the surface of a medical device ***(corresponding to the medical device of the claimed invention)*** such as a catheter ***(corresponding to the catheter of claim 14)*** (Column 9, lines 20-45). The Examiner takes the position that the portion of the substrate beneath the grafted surface corresponds to the polymer bulk film of claim 6. Furthermore, the determination of patentability for product claims containing process limitations is based on the product itself and not on the method of production. If the product is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) and also see MPEP 2113.* In this case, the product (i.e., the medical device or the catheter) is the same despite the process limitation of plasma polymerizing the functionalized coating. All limitations of the claimed invention are either inherent or disclosed in the above reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okuda et al. (US 6,053,939).

Okuda et al., as discussed above, do not disclose that the covalently bonded or grafted functionality has a thickness of 10nm to 150nm. However, it would have been obvious to one having ordinary skill in the art to optimize the thickness of the covalently bonded functionality given that the thickness of the grafted layer can be controlled by controlling the amount of crosslinking agent present in the solution.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (US 6,099,563).

Zhong, as discussed above, do not disclose that the covalently bonded or grafted functionality has a thickness of 10nm to 150nm. However, it would have been obvious to one having ordinary skill in the art to optimize the thickness of the covalently bonded functionality given that the thickness of the grafted layer can be controlled by controlling the amount of crosslinking agent present in the solution.

6. Claims 12, 13, 15, 16, 19, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis-Lemessy et al. (US 6,139,525) in view of Zhong (US 6,099,563).

Davis-Lemessy et al. disclose a catheter having a first catheter part formed of a first polymeric material and a second catheter part formed of a second polymeric material fusion bonded to the first catheter part. The catheter includes an elongated catheter shaft comprising at least one tubular member and an inflatable balloon on a distal portion of the shaft (Column 2, lines 13-30) The shaft is preferably made of a material in the polyethylene family such as HDPE while the balloon is a polyamide material such as nylon (Column 3, lines 30-45). Davis-Lemessy et al. do not specifically teach that the catheter comprises a covalently bonded functionality. However, Zhong, as discussed above, discloses bioactive substrate coating for medical devices, which enhance the antithrombogenic nature of such devices (Column 1, lines 15-22) and renders them biocompatible. Accordingly, it would have been obvious to one having ordinary skill in the art to coat the catheter disclosed by Davis-Lemessy et al. with a covalently bonded functionality given that Zhong specifically teaches that doing so would renders the catheter antithrombogenic and biocompatible.

7. Claims 15, 17, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (US 5,752,934) in view of Zhong (US 6,099,563).

Campbell et al. disclose balloon catheters comprising a continuous catheter tube and a balloon at the end of the catheter tube (Column 2, lines 38-43). The balloon

portion of the catheter is made of porous expanded polytetrafluoroethylene (Column 2, lines 62-65) having a microstructure of interconnected fibrils (Column 3, lines 46-50) and an elastomer (See claim 25). Campbell et al. do not specifically teach that the catheter comprises a covalently bonded functionality. However, Zhong, as discussed above, discloses bioactive substrate coating for medical devices, which enhance the antithrombogenic nature of such devices (Column 1, lines 15-22) and renders them biocompatible. Accordingly, it would have been obvious to one having ordinary skill in the art to coat the catheter disclosed by Campbell et al. with a covalently bonded functionality given that Zhong specifically teaches that doing so would renders the catheter antithrombogenic and biocompatible.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheeba Ahmed whose telephone number is (703)305-0594. The examiner can normally be reached on Mon-Fri 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Thibodeau can be reached on (703)308-2367. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)306-5665.

Sheeba Ahmed
July 29, 2002

Vivian Chen
Primary Examiner